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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,745	01/22/2002	Brendan M. Donohoe	057	3564
33109	7590	11/17/2004	EXAMINER	
CARDICA, INC. 900 SAGINAW DRIVE REDWOOD CITY, CA 94063			BUI, VY Q	
			ART UNIT	PAPER NUMBER
			3731	
DATE MAILED: 11/17/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/054,745

Applicant(s)

DONOHUE, BRENDAN M. ET AL

Examiner

Vy Q. Bui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) 2,7 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,8-12,16,17,20-22,25-35,37,42 and 52-61 is/are rejected.
- 7) ☒ Claim(s) 13-15,19,23,24,36,38-41 and 43-51 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date p.3 of IDS 5/11/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-5, 8-12, 17, 19, 20, 22, 25, 26, 27, 30-35, 37, 42, 54, 57, 58, 60, and 61, are rejected under 35 U.S.C. 102(b) as being anticipated by Dekel 5,591,187. Note the rejections will flip the names of the cutting elements, as the different claim limitations require reinterpretation of the reference. Dekel discloses, "a tool for making an incision in and removing tissue from a vessel wall (the whole device), comprising: a cutter (13)', and a piercing member (20) positioned within said cutter, wherein said piercing member and said cutter are configured to translate together to penetrate the wall of the vessel (the cutting members are structured to allow the tool to move as one unit".

Regarding claim 3, the piercing member is element 13 and the cutter is element 34.

Note,

the piercing member and cutter are now fixed rotationally.

Regarding claim 4, wherein said cutter (34) is a curved blade having a substantially circular distal end.

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Regarding claim 5, wherein said cutter is a curved blade having an open perimeter (there opening along the perimeter of the cutter) at its distal end and along the length of the whole cutter.

Regarding claim 8, wherein the distal tip of said piercing member (13) extends further in the distal direction than the distal end of said cutter.

Regarding claim 9, wherein said piercing member (20) holds the tissue removed from the wall of the vessel (cutter is 13).

Regarding claim 10, wherein said cutter (13) is substantially hemostatic.

Regarding claim 11, wherein said piercing member is an auger.

Regarding claim 12, wherein said auger and said cutter are substantially coaxial.

Regarding claim 17, Dekel discloses "a surgical tool for removing tissue from the wall of a vessel to create an opening, comprising: a rotatable cutter (13)4 an auger assembly (20) fixed (fixed as in attached. To be clear, element 13 is considered to be sxed to element 20, via the rod extending from element 13) to and substantially coaxial with said cutter, said auger assembly comprising an auger (20) at its distal end; an actuator (22) connected to at least one of said auger assembly and said cutter.

Regarding claim 19, the actuator (21) of Dekel is attached to auger (20) via the rod (22).

Regarding claim 20, wherein said actuator is retractable (Dekel discloses the tool can be disassembled.)

Regarding claim 22, wherein said cutter is vented. Vented can be exposed to air. Such as John vented his shorts out the window. Since element 13 is movable outside the casing 18, it is considered to be vented.

Regarding claim 25, further comprising a casing, said casing comprising a contact structure (8) at its distal end, wherein said auger and said cutter translate relative to said contact

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structure.

Regarding claim 26, wherein said contact structure has an open perimeter.

Regarding claim 27 wherein said auger and said cutter translate distally a selected amount relative to said contact structure.

Regarding claim 30, further comprising a seal housing (32), and an introducer tip (8) connected to said seal housing, wherein said auger (20) and said cutter (13) are configured to slide through said introducer tip.

Regarding claim 31, wherein said auger and said cutter are configured for withdrawal into said seal housing.

Regarding claim 32, wherein said introducer tip is expandable. The introducer can be inherently expanded by heating for example.

Regarding claim 33, wherein said seal housing comprises at least one guide (D3).

Regarding claim 34, further comprising a bushing (see attached sheet D1, previous "Office Action") connected to said actuator, said bushing comprising at least one guide follower (D2) configured to engage said guide.

Regarding claim 35, wherein said introducer defines a first axis, and wherein said guide extends away from said first axis.

Regarding claim 37, wherein the distal end of said auger extends distally beyond the distal end of said cutter.

Regarding claim 42, as best understood wherein said at least one rib (each coil in the 32 is a rib) extends substantially axially along said first driveshaft (18).

Regarding claim 54, Dekel discloses, "A method for creating an opening in a vessel wall within a patient, comprising: advancing a piercing member and a cutter through the vessel wall, said cutter axially fixed to and positioned at least partially around said piercing member, wherein

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said advancing cuts tissue from the vessel wall; and retracting said piercing member and said cutter, whereby the cut tissue is removed from the vessel wall to form an opening therein."

Regarding claim 57, further comprising providing hemostasis at the opening. This will be done automatically by the body through the natural healing process.

Regarding claim 58, further comprising rotating said auger and said cutter.

Regarding claim 60, wherein said auger pulls the vessel wall proximally while said cutter advances distally.

Regarding claim 61, wherein said auger holds the tissue plug intramurally.

Claim 17 and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Donohoe.

The cutter is element 28. The auger is 26.

The two cutting elements are attached together or fixed together. However, they are not rotatably locked. The actuator is element 30.

Regarding claim 21, wherein said actuator extends away from the axis of said cutter.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dekel-'187 in view of Mueller 200 1/0001 124.

Dekel discloses a sharp cutting element but does not go into detail about which direction to make the bevel to give the cutter a sharp edge. Mueller discloses a circular tissue-puncturing tool. Mueller teaches the cutting edge may be beveled inwardly or outwardly. At the time of the invention it would have been obvious to one having ordinary skill in the art to make the bevel of

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the Dekel tool beveled inwardly as taught by Mueller, because an inward bevel enables' the edge to pierce the tissue.

Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dekel-5,591,187. The Dekel device discloses the device of claim 17 and a handle. Dekel doesn't disclose a knob (18) operatively connected to said actuator. A knob is not disclosed. Knobs perform the same function as the handle of Dekel, allowing the actuator to be rotated. At the time of the invention it would have been obvious to one having ordinary skill in the art to substitute a knob for handle since knob would perform equally well as the handle in Dekel device.

Regarding claim 29, wherein said knob is rotatable through two or more positions (to place the knob in position B), and wherein actuation (position A is shown in figure 1, a 90-degree rotation will place the knob in position B) and wherein actuation of said auger (16) and said cutter (13) is controlled by rotation of the knob.

Claims 16, 52, and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dekel-'187 in view of Donohoe et al-2002/0082626.

Regarding claim 53, the Dekel device contains an auger but does not contain a flute on the auger. The auger on the Donohoe et al. device comprises a flute. The auger of Donohoe functions to remove and hold the tissue in same manner as the Dekel device. At the time of the invention it would have been obvious to one having ordinary skill in the art to substitute the Donohoe et al auger for the Dekel device since the Donohoe device is an alternate analogous structure and is capable of removing and holding a piece of tissue.

Regarding claim 53, the combined Dekel has an auger of the same structure as the applicant's. Thus the auger of Dekel would inherently have the capability to pull the tissue proximally faster than said cutter advances.

Claims 55-56 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dekel-'187 in view of Gannoe et al. 6,488,693.

The Dekel device is manually operated. Dekel does suggest that this tool can be operated via a hydraulic mechanism. He also discloses that spring could apply an impulsive force in the reverse direction. The advancement of the auger is not automated by Dekel. Gannoe et al. discloses using a spring mechanism to advance the cutting member. This mechanism automates the manual process disclosed by Dekel.

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At the time of the invention it would have been obvious to one having ordinary skill in the art to automate the forward force of the Dekel device by implementing the spring mechanism of Gannoe et al., since it has been that broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art.

Allowable Subject Matter

Claim 13-15, 23-24, 36, 38, 39, 40, 41, 43, 44, 45-51 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Regarding claims 13-15, Dekel does not disclose an auger that comprises: a spike (the tip of the auger is the spike); a shaft (20) connected to and extending distally from said spike, said shaft fixed to said cutter. There are insufficient structural elements in Dekel to anticipate all the limitations of this claim.

Regarding claims 23 and 24, the Dekel device doesn't contain a flange that centers the auger.

Regarding claim 36, 38, 39, 40, 41, 43, 44, 45-51, the axis of the introducer and the actuator are on the same axis.

Response to Arguments

Applicant's arguments filed 5/11/2004 have been fully considered but they are not persuasive.

At least independent claims 1 and 17 are not clearly defined over Dekel-'187. Dekel-'187 does disclose auger 20 within rotatable cutter 13, wherein both auger 20 and cutter 13 can be translated together and at least actuator 14 connected to auger 20 (Fig. 1).

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Information Disclosure Statement

The references listed on page 3 of IDS filed 5/11/2004 have been considered and initialized as attached.

Conclusion


THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is 703-306-3420. The examiner can normally be reached on Monday-Tuesday and Thursday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T Nguyen can be reached on 703-308-2158. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


11/15/2004

VY BUI
PRIMARY EXAMINER